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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,772	12/03/2001	Joaquina Faour	PHUS-7	7970

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/004,772

Applicant(s)

FAOUR ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt of amendment dated 9-20-04, remarks and Oath dated 8-20-04 is acknowledged.

Claims 1-55 are pending in the instant application.

#### ***Response to Arguments***

In response to the amendment, examiner has withdrawn the following rejections:

1. Claims 1-55 rejected under 35 USC 112, 2<sup>nd</sup> paragraph, as failing to comply the written description requirement.
2. Rejection of claim 36 as a substantial duplicate of claim 1.
3. Defective Oath.

Applicant's arguments filed 8-20-04 have been fully considered but they are not persuasive.

#### **Double patenting rejection:**

Applicants argue that the reissue application herewith has an effective filing date of May 29, 1998 (the filing date of the Patent 6,004,582) and that any patent issuing from this application would already have an expiration prior to the expiration date of the cited patents for Double patenting rejection and therefore, the issuance of the instant claims would not result in an "unjustified extension of the rights granted in the first patent". Applicants argue that filing of the terminal disclaimer in the instant application is improper and would actually result in an unwarranted extension of the term of the ensuing patent. Applicants' arguments are not persuasive because double patenting rejection prevents not only improper timewise extension of the "rights to exclude" granted by a patent but also prevents possible harassment by multiple assignees (as stated in the statute, please refer to the previous action). In the instant case, a filing

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of the terminal disclaimer does not extend the term of the U.S. Patent No. 6,004,582, as argued by applicants. Therefore, the rejection is proper.

Applicants argue that instant claims are patentably distinct from the claims of '357 patent and the '302 patent because '582 patent (parent patent for this reissue application) and states that the '582 patent was cited and overcome during the prosecution of the '655 application thereby establishing prima facie case of patentability over the entire subject matter disclosed in the '582 patent. Applicants' argument is not persuasive because double patenting rejection is based upon the scope or breadth of the claimed subject matter and whether instant claims as presented overlap with the subject matter of the patented claims (not disclosure) so as to provoke improper timewise extension or possible harassment by multiple assignees, if issued. In this instant case, the claims of '357 patent also recite an osmotic device having the same design as that of the instant drug delivery system and further include specific drugs. Instant independent claims do not recite specific drugs. However, instant drug delivery system can be applied to any kind of drugs including that claimed in '357 because both instant and the patented system have the same design and also recite different release patterns. With respect to patent '302, applicants argue that the basis for patentability of the claims was the specific combination of oseltamivir and an H1 antagonist to achieve specific relelase profiles, whereas instant claims do not mention any specific combination. Applicants' arguments are not found persuasive because instant claims broadly recite a first active agent and a second active agent and further recites a variety release profiles. Applicants also agree that independent claims of '302 do disclose a multilayered device. Therefore, the double patenting rejection has been maintained.

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Rejection over Guittard in view of Ayer et al:

Applicants argue that examiner appears to equate the microporous lamina of Guittard with the instant inert polymer coat and argues that the microporous lamina of Guittard acts in concert with the semipermeable membrane to form an integral laminated wall that maintains its physical and chemical integrity and does not separate into lamina during the operation of the device, thus forming a bi-layered wall, which is different from the operation and structure of the instant device of claims 24-35 and 40-55, which requires that the inert coat be completely erodible or water soluble (even though the semipermeable membrane maintains its physical and chemical integrity). Applicants' arguments have been considered but not found persuasive because on one hand applicants state that the unique properties of the instant drug delivery system are due to presence of the poly(vinylpyrrolidone)-(vinyl acetate) in the polymer coat surrounding the semipermeable membrane. On the other hand, applicants themselves admit in the instant specification that exemplary polymers that constitute the polymer coat are those described in US patent No. 4,576,604 (Guittard), which is the same patent cited under this section for rejecting instant claims. Thus, if the unique advantages are due to the above polymer, then instant claims 24, 36 and 50, which do not recite the above polymer, should not possess the above unique properties. Alternatively, if the exemplary polymers (described by incorporation of the reference) also possess the same properties, examiner cited the same reference, which applicants are relying upon. Accordingly, applicants' argument that the reference does not teach applicants' invention is moot. The properties of the polymers are inseparable from the polymers, unless shown otherwise.

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Applicants also argue that Guittard and Ayer fails to provide the missing elements, as Ayer requires the formation of a distribution zone between the semipermeable membrane and an exterior membrane and a water soluble layer between the semipermeable membrane and the distribution zone in which the drug and fluid are present, whereas Guittard requires two laminas are required for proper functioning. It is argued that Ayer would not be motivated to make the exterior lamina water-soluble or water erodible, since doing so would result in an osmotic device that has no distribution zone, and Ayer does not contemplate such a device. As with Guittard, applicants argue that Ayer requires that two laminas retain their physical integrity during operation of the device. Applicants conclude by arguing that the prophetic device that would result from the combined teachings of Ayer and Guittard result still requires two laminas and is different from and less advantageous compared to the instant device. Applicants' arguments are not found persuasive because the motivation to combine the teachings of Ayer with that of Guittard et al comes from the teaching of Ayer to cover or plug the passage way in the semipermeable membrane (of Guittard et al) with a polymer membrane. Applicants' argument that Ayer requires a distribution zone is moot because both Guittard and Ayer teach an osmotic device having the same structural design i.e., a core, surrounded by a semi-permeable membrane with a passage way, covered by a microporous lamina and further comprising an external coat. Accordingly, plugging the passage way (as taught by Ayer) improves the properties of drug dispensing system of an osmotic device with a semipermeable membrane and a microporous lamina.

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***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

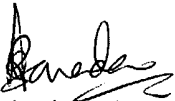
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
December 29, 2004

THURMAN K. PAGE  
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